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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,653	10/03/2000	Peter Daniel Christian	A-58631-4/RFT/DJM	7496
7590	01/15/2004		EXAMINER	
Flehr Hohbach Test Albritton & Herbert Four Embarcadero Center Suite 3400 San Francisco, CA 94111			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 01/15/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/677,653	CHRISTIAN ET AL.
	Examiner Zachariah Lucas	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 10-22-2003.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 15-24 is/are pending in the application.

4a) Of the above claim(s) 24 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 15-23 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) Notice of References Cited (PTO-892)                            4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                    6) Other:

## DETAILED ACTION

### *Status of the Claims*

1. Currently, claims 15-24 are pending in the present application. Claims 15-23 are under consideration, and were rejected in the prior action (mailed on June 6, 2002). Claim 24 has been withdrawn from consideration as to a non-elected invention.
2. This action is being made Non-Final because it raises new grounds of rejection not made in the prior action, and not necessitated by amendment.

### *Specification*

3. **(Prior Objection- Withdrawn)** The specification was objected to in the prior Office action for not citing all of the parent application to which priority was claimed in the first paragraph of the application. In view of the Applicant's arguments, the objection is withdrawn.
4. **(Prior Objection-Withdrawn)** The disclosure was objected to because of an informality on line 17 of page 11. in view of the amendment to the specification, the objection is withdrawn.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Restated and Maintained)** Claims 15-19, 21, and 22 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on nucleic acids comprising a first sequence encoding an insect RNA virus capsid protein, and a second sequence that either is, or encodes a protein that is, insecticidal. Among the insecticidal sequences claimed by the applicant are antisense sequences and ribozymes. The claim was rejected because the applicant has provided no written description support for such ribozymes or antisense sequences.

The Applicant traverses this rejection for substantially the same reasons as argued previously. The Applicant indicates that claimed invention reads on nucleic acids encoding a delivery device for an insect toxin, and the toxin, and that the application provides examples of insecticidal compounds that may be encoded by the claimed nucleic acid sequence. The Applicant concludes that because the claimed sequence is directed to a nucleic acid sequence that encodes or is an insect toxin and a viral capsid to act as a carrier or the toxin, and because the carrier may be used with any nucleic acid, the Applicant has provided adequate written description for any nucleic acid comprising a sequence that is or encodes a toxin. This argument is not found persuasive.

On pages 5-6 of the Response, the Applicant points out several toxins that have been identified in the art and in the present specification. However, none of these insecticidal toxins are either antisense or ribozyme sequences. Thus, while the Applicant's disclosed mode of delivery may be effective for the delivery of antisense or ribozyme sequences if known, there is

no indication that the Applicant is in possession of any such sequences. In the present case, the Applicant is attempting to claim a genus of inventions, those comprising insecticidal nucleic acid sequences, that have been identified solely by their function (as insecticidal toxins). As the Applicant has not provided any examples or structures to demonstrate that they were in possession of the genus, the claims lack written description support to the extent that they read on such nucleic acids. For the reasons above, and for the reasons of record, the rejection is maintained.

7. **(Prior Rejection- Reformed and Maintained)** Claims 15-19, and 21-23 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification while being enabling for isolated nucleic acids comprising the a first sequence encoding an insect RNA virus capsid protein and a second sequence that encodes an insecticidal protein, does not reasonably provide enablement for the claimed nucleic acids where the second sequence is a ribozyme, antisense, or other insecticidal nucleic acid sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claims have been described above. It is noted that the rejection previously indicated the Applicant was enabled for embodiments wherein the ribozyme was one of those on pages 14-15 of the application. However, as these ribozymes are not disclosed as insecticidal, the rejection is restated such that the Applicant is not enabled for the use of any insecticidal ribozymes or antisense sequences as no such sequences have been described by either the Applicant or the art.

The Applicant traverses the rejection on the basis that the claimed invention overcomes some of the problems in the prior art (those of delivering the nucleic acids) and that “the specific identities of the nucleic acids need not be determined until the invention is to be used.” While the Examiner agrees that the claimed invention satisfies the problems of delivery, and that in this case the toxicity of the nucleic acids is irrelevant, the Applicant is still not enabled for the claimed invention because there is no identification of, nor any guidance towards, antisense or ribozyme sequences that have insecticidal effects.

In contrast the Applicant’s assertion that the nucleic acids need not be identified until they are to be used, the rule for satisfying the enablement requirement is that the application must enable those in the art to make and use the claimed invention without undue experimentation. See e.g., MPEP 2164. Applicant’s unsupported assertion that those in the art would be able to easily identify such antisense and ribozyme sequences is noted. However, the Applicant provides no evidence that this is in fact the case. Further, the art references cited in the prior action do not support the assertion. See e.g., Braasch, Branch, and Gewirtz (teaching the unpredictability and complexities in the identification of antisense and ribozyme technology). It is therefore not sufficient for the Applicant to indicate that those in the art may use the claimed invention to deliver antisense and ribozymes in the present case because there is no indication that those in the art would be able to easily identify such molecules. Because the Applicant has not enabled those in the art to use antisense and ribozymes as insecticides, the Applicant is not enabled for nucleic acids comprising such sequences. The rejection is therefore maintained.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **(Prior Rejection-Maintained)** Claims 15, 16, and 19-23 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Wilcox in view of Harley et al. (Virology 69:323-326). The Applicant traverses this rejection on the grounds that the Harley and Wilcox references do not teach or suggest the claimed invention. The Applicant provides three arguments in support of their traversal. First, the Applicant appears to be arguing (page 10, second paragraph) that there is no motivation to combine the Harley and Wilcox references because Harley does not teach that the viral capsids disclosed therein target the gut of the insects as do the targeting moieties of Wilcox. The Applicant also argues that the nucleic acid encoding the hybrid of Wilcox varies structurally from the construct of the presently claimed invention. Response, pages 10-11). Finally, Applicant argues that the teachings of the two references do not teach that the expression of the nucleic acid that would result from the combination would not result in the protection of the toxin moiety from degradation, as would be the case with the expression of the claimed nucleic acids.

The traversals are not found persuasive. First, with respect to the motivation to combine the Wilcox and Harley references, the Applicant argues that those in the art would have had neither motivation to combine the references. However, those in the art would have been aware that the capsid proteins of the virus would be the source of the virus' host range. See e.g., Chang

et al., J Virol 66: 6858-67 (teaching that the host range of the parvovirus is determined by the capsid proteins). From the teachings on the Harley reference, those in the art would have had a reasonable expectation that the virus disclosed therein targeted the insect gut. Thus, it would have been obvious to those in the art to use the capsid protein from the CPV virus described in Harley as a targeting moiety in the Wilcox hybrid.

Because the art indicates that the capsid proteins of CPV target insect cells, and the purpose of the targeting moiety in the Wilcox reference is to target the toxin conjugate to such cells, it would have been obvious to those in the art to use these capsid proteins in the conjugates of Wilcox. While neither reference explicitly directs those in the art towards the claimed invention, the teachings of Wilcox indicate that any protein capable of so directing the toxin conjugate would be useful. Thus, while the references do not independently render the claimed invention obvious, their combined teachings do. The Applicant's additional argument that the Wilcox fusion is not the same as the claimed nucleic acid construct is not found persuasive because the reference teaches the making of hybrid nucleic acids encoding the fusion proteins. See e.g., column 1, lines 44-49. Thus, the reference teaches the making of nucleic acid constructs encoding the chimeric toxins. Because such nucleic acid constructs would include a sequence encoding the targeting moiety (the capsid proteins indicated by Harley) and a sequence encoding a toxin, the construct suggested meets the limitations of the rejected claims.

With respect to the third argument in traversal, that there is no indication that the nucleic acid of Wilcox and Harley would be delivered to the gut of an insect. This argument is not found persuasive for two reasons. First, the claims merely read on a nucleic acid comprising a sequence encoding a small insect RNA virus capsid and a second sequence that is, or encodes, an

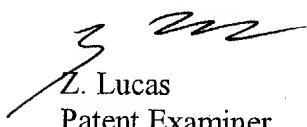
insecticidal molecule. Such a nucleic acid is described by the art. While the art may not provide any indication that the nucleic acid is itself delivered to an insect cell, there is also no such requirement in the claim. While the Applicant argues that capsovectors protect the toxin moiety from degradation, the present claims are not drawn to capsovectors, but to nucleic acids encoding the components thereof. Thus, the activities of the complete capsovector are not relevant to the patentability of the presently claimed invention. For these reasons, and for the reasons in the prior actions, the rejection is maintained.

### ***Conclusion***

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
January 8, 2004

  
JAMES C. HOUSEL 1/12/04  
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